510(k) Summary

JAN 13 2009

General Provisions

The name of the device is:

Proprietary Name	Common or Usual Name
Outback® LTD™ Re-Entry Catheter	Catheter, percutaneous 21 CFR 870.1250 Product Code: DQY

Name of Predicate Devices

The device is substantially equivalent to:

- **Outback LTD Re-Entry Catheter** (510(k) # K043534)

Classification

Class II

Performance Standards

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

Indication for Use

The Outback LTD Re-Entry Catheter is intended to facilitate placement and positioning of guidewires and catheters within the peripheral vasculature. The Outback LTD Re-Entry Catheter is not intended for use in the coronary or cerebral vasculature.

Device Description

The **Outback LTD Re-Entry Catheter** is a sterile (via Ethylene Oxide sterilization) device and is intended for single use only.

Summary of Substantial Equivalence

The **Outback LTD Re-Entry Catheter** is substantially equivalent to the predicate device. The substantial equivalence to the predicate device has been demonstrated via data collected from non-clinical *in-vitro* bench testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Cordis Corporation
Ms. Karen Wilk
Regulatory Affairs Manager
7 Power Horn Drive
Warren, NJ 07059

Re: K083814
Trade/Device Name: Outback LTD Re-Entry Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: December 19, 2008
Received: December 22, 2008

SEP 18 2013

Dear Ms. Wilk:

This letter corrects our substantially equivalent letter of January 13, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083814

Device Name: Outback LTD Re-Entry Catheter

Indication for Use: The Outback LTD Re-Entry Catheter is intended to facilitate placement and positioning of guidewires and catheters within the peripheral vasculature. The Outback LTD Re-Entry Catheter is not intended for use in the coronary or cerebral vasculature.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Thanh

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083814